

## REMARKS

This Rule 116 Amendment is responsive to the Office Action dated December 27, 2010. In the application claims 44-52 are pending. Claims 44-52 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,478,791 to Carter et al. in view of U.S. Patent No. 6,592,596 to Geitz, and in further view of U.S. Patent No. 5,250,075 to Badie. Because the Final Office Action does not address the issues raised in the prior amendment, this Rule 116 paper is proper so that the application may be placed in better condition for appeal should resolution not be reached. In view of the foregoing, Applicant respectfully requests reconsideration of the claims in view of the remarks presented below.

### **Claim Rejections Under 35 U.S.C. §103**

Claims 44-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,478,791 to Carter et al. in view of U.S. Patent No. 6,592,596 to Geitz, and in further view of U.S. Patent No. 5,250,075 to Badie. In the Office Action, the Examiner argues that in Figures 9A and 9B of Carter, grooves/channels for receiving tissue is shown. This is asserted without any citation to Carter evidencing this fact, and Applicant respectfully submits that this is not the case. Applicant believes that the Examiner has misread the Carter reference. The entire discussion of Figures 9A and 9B of Carter can be found in Column 8 between lines 35 and 51. In those 16 lines, there is nothing that supports the Examiner's position that tissue is acquired in grooves. In fact, the disclosure of Carter reveals quite the opposite. Carter states that:

*"Arms 52 again have roughened **surfaces** 36 to engage and draw the fascial **surface** inward. As the grasping arms close toward each other, roughened fold retainers 54 move distally relative to shaft 42, thereby urging the tissue surface to form fold 22 in the desired direction."*

And

*"Channels 56 provide access to the approximated tissues when the arms are adjacent to each other. Staplers 58 ride within channels 56, and can be advanced distally to deploy fasteners 24 . . . while the roughened fold retainers 54 extend within the folded tissue surfaces."*

From the foregoing, it is clear that the embodiment of Figures 9A and 9B do not acquire tissue within grooves as contended by the Office Action. The outer surface 36 (i.e., the extreme edge of the device) pulls the surface of the tissue. No tissue enters the grooves due to the surface to surface contact. At least the Office Action has not proven that tissue enters the grooves. Further, there is a rod 54 that extends distally as the arms are closing to **ensure** that the tissue folds **away** from the grooves to prevent tissue from entering the grooves. The reference further states that the channels are present to allow the stapler access to the tissue, which infers that the channels are unobstructed by any tissue which would impede the movement of the stapler. Taken collectively, the evidence demonstrates that no tissue is present in the channels as contended by the Office Action and the rejection based on Carter is flawed and incorrect.

The sixteen lines of text in the Carter disclosure describing Figures 9A and 9B on which the Office Action maintains is the basis for the rejection has nothing that supports the Office Action's position. Rather, there is only evidence that supports Applicant's position that no tissue enters the grooves of arms. It is inappropriate to place this application in "Final" status and compel the Applicant to go to appeal without knowing the very evidence the Examiner is relying upon to support the rejection. If there is support in the Carter disclosure that Applicant has missed clearly showing that tissue enter the grooves of the embodiment of FIGS. 9A and 9B, the Office Action did not identify where such support is located. If the support is expressed, then the column and line numbers of the disclosure where it states that tissue is acquired "within" the grooves of the device as contended by the Office Action should be provided. If the Examiner is

relying on personal knowledge of the device, that information should be set forth in the record so Applicant may have a fair opportunity to address such personal knowledge. If the Examiner is relying on inherency, there are procedures in place that have not been complied with in regards to a rejection based on inherency. Namely:

*"when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." MPEP Section 2131*

No such extrinsic evidence was produced by the Office Action. Since there has been no expressed showing that tissue enters the grooves, and no evidence showing that tissue *necessarily* enters the grooves, and Applicant has provided ample evidence that tissue *cannot* enter the grooves, the final rejection must be withdrawn so that Applicant may have a fair opportunity to address the rejection based on evidence of record in this case.

In view of the foregoing arguments, it is respectfully submitted that the rejection of the pending claims cannot stand, and Applicant further asserts that the claims as presented are in condition for allowance. Applicant requests that the pending rejections be withdrawn and a notice of allowance entered. However, at the very least a new, non-final office action should be entered after withdrawal of the final office action, with evidence or citation to the Carter disclosure demonstrating clearly the position taken by the Examiner.

If the Examiner believes that a telephone conference will further the prosecution of this case, the Examiner is invited to contact the undersigned at the number below.

The Commissioner is authorized to charge any deficiencies or fees in connection with this amendment to Deposit Account No. 06-2425.

Respectfully submitted,

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